

27th September 2017

URGENT - FIELD SAFETY NOTICE

Commercial Name		Pilling® Knife Handles	
Teleflex Reference:		EIF-000186	
Type of Action		Recall	
Product Code	Lott Number	Product Code	Lott Number
352950	D6	352953	B6
	E6		E6
	F6		I6
	G6	352957	A6
	H6		B6
	I6		B7
	J6		K6
352951	I6	L6	
	J6		
352952	H6		

Dear Customer,

Details of affected devices

Teleflex has initiated a voluntary Field Safety Corrective Action for the above listed product codes.

Description of the problem

The products referenced above are reusable surgical knife handles, which are intended for use with blades which are inserted into a slot in the handle. Teleflex Medical is recalling the knife handles because the slot depth is out of specification, so blades may not fit on the handles properly. If a blade does not fit properly, the user may struggle to connect the two pieces, causing them to slip and cut their hand. Or, if the blade is not securely connected when the product is used in surgery, the blade could dislodge during use and fall into the body cavity. Teleflex Medical has received no reports of any patient injuries or deaths relating to the recalled products. Teleflex Medical is recalling these products in an effort to provide our customers and their patients the highest quality product possible.

Our records indicate that you have received products that are subject to this recall. We are now notifying our customers to take the following actions:

FIELD SAFETY CORRECTIVE ACTION INSTRUCTIONS

ADVICE ON ACTION TO BE TAKEN BY MEDICAL STAFF

1. We request that you check your inventory for product within the scope of this field action. Users should cease use and distribution of stock of the affected product batch and quarantine immediately.
2. If you do not have stock in scope of this field action as referred to in above table then mark the according checkbox on the Acknowledgement form (Appendix 1) and return the form to the fax number or e-Mail-address mentioned below.
3. If you have stock from the affected product as referred to in above table, mark the according checkbox on the Acknowledgement form (Appendix 1). Contact customer service by calling the phone number

mentioned below who will issue you with a return number. Write this return number into the respective field in the Acknowledgement form.

4. Complete 'Appendix 1' for all products in your possession and under control. Return this form immediately to Customer Service.
5. Teleflex (or your local dealer) will issue a credit note upon receipt of the returned affected product.

INSTRUCTION FOR DISTRIBUTORS OF AFFECTED PRODUCT

6. If you are a distributor, provide this field safety notice to all of your customers who have received product in scope of this Field Action. Your customer is then required to complete the acknowledgement form and return this to you.
7. As a Distributor you are required to confirm to Teleflex that you have completed the field activity outlined above. Upon completion of your actions, please forward the completed Acknowledgement Form to Customer Service.
8. Please be aware that all European Economic Area/Switzerland (EEA/CH) and Turkey Member State Competent Authorities in which Teleflex distribute directly will be notified by Teleflex.
9. If you are a distributor and/or have a reporting responsibility within or outside the EEA/CH/TK area, please notify your local Competent Authority of this action. Please forward the notification and all communication with your local competent authority to Teleflex.

Teleflex

Teleflex informs all customers, employees of Teleflex and distributors on this Field Action.

Transmission of this Field Safety Notice

This notice should be passed on to all persons who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. Please consider end users, clinicians, risk managers, supply chain/distribution centres etc. in the circulation of this notice.

Maintain awareness of this notice until all required actions have been completed in your organisation.

Contact reference person

Should you require any further information or support concerning this issue, please contact:

Customer Service:

Contact: Carine Fournier

FAX: +05 62 18 79 82

Telephone: 05 62 18 79 41

Email: productcomplaints.france@teleflex.com

Please be advised that all European Economic Area/Switzerland (EEA/CH) and Turkey Member State Competent Authorities to which Teleflex distribute directly will be notified by Teleflex. Teleflex is committed to providing high quality, safe and effective products. We sincerely apologize for any inconvenience this action may cause you or your patients. If you have any other questions, feel free to contact your local sales representative or Customer Service.

For and on behalf of Teleflex,


Padraig Hegarty VP, QA

FIELD SAFETY CORRECTIVE ACTION
ACKNOWLEDGEMENT FORM

PRODUCT FIELD ACTION BY TELEFLEX - IMMEDIATE ATTENTION REQUIRED

Ref. EIF-000186

RETURN COMPLETED FORM IMMEDIATELY TO:

FAX: 05 62 18 79 82

Email: productcomplaints.france@teleflex.com

<input type="checkbox"/> We confirm receipt of this FSN and completed the required actions contained therein. We confirm that our inventory does NOT include products affected by this Field Action.	<input type="checkbox"/> We confirm receipt of this FSN and completed the required actions contained therein. We confirm our inventory DOES include products affected by this Field Action. The use and further distribution of the affected products is stopped. All products are put on hold and the amount below will be returned. Return Authorisation No _____
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PLEASE PRINT PRODUCT QUANTITY NUMBERS CLEARLY.

COMMERCIAL NAME OF AFFECTED PRODUCTS:	Pilling® Knife Handles	
PRODUCT NUMBER	LOT NUMBER	QUANTITY (Returning)
<ul style="list-style-type: none"> Include a copy of the completed Acknowledgement Form in the returns package with the returned units Ensure the RAN number is clearly visible on the returns package. Please label returns as "Field Action Returns" 		

Complete this Acknowledgement form and return immediately by using the fax number or e-mail address above.

INSTITUTION NAME (EG NAME OF HOSPITAL, HEALTH CARE ORGANISATION)	
INSTITUTION ADDRESS	Phone / Fax
FORM COMPLETED BY:	Stamp
PRINT NAME: _____	
SIGNATURE: _____	
DATE	